

JUL 18 1996

K961502

SPAN-AMERICA

MEDICAL SYSTEMS, INC.

510 SUMMARY LUBRICATING JELLY, LOW VISCOSITY

- 1.0. **SUBMITTER:** Span-America Medical Systems, Inc.
ADDRESS: 70 Commerce Center; Greenville, SC 29615
TELEPHONE: 864-288-8877
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- CONTACT PERSON:** Wanda J. Totton, Director of Quality
Polly Thompson, Manager of Quality Assurance
- DATE PREPARED:** April 15, 1996
- 2.0. **TRADE NAME:** Lubricating Jelly
- COMMON NAME:** Lubricating Jelly
CLASSIFICATION NAME: Lubricant, Patient
- 3.0. **PREDICATE DEVICE:** Lubricating Jelly, 510K882506
- 4.0. **DESCRIPTION:** Lubricating Jelly is a patient lubricant intended for medical purposes that is used to lubricate a body orifice to facilitate entry of a diagnostic or therapeutic device.
- 5.0. **INDICATIONS FOR USE:** To lubricate a body orifice to facilitate entry of a diagnostic or therapeutic device.
- 6.0. **SUBSTANTIAL EQUIVALENCE:** The product is similar in function and intended use to Lubricating Jelly, 510K882506.

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